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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,167	09/21/2006	Kimihiro Mabuchi	19461-006US1 548063	5242

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EXAMINER	
MENON, KRISHNAN S	
ART UNIT	PAPER NUMBER
1797	

NOTIFICATION DATE	DELIVERY MODE
02/23/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary	Application No.	Applicant(s)	
	10/599,167	MABUCHI ET AL.	
	Examiner	Art Unit	
	Krishnan S. Menon	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) *7-15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6 and 16-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are pending as amended 1/22/10, of which claims 7-15 are withdrawn.

Claim Rejections - 35 USC § 102

Claims 1-6 and 16-23 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Shimagaki et al (US 6,103,117)

Claim interpretation: Applicant's claim 1 recite a perm-selective membrane made from polysulfone and polyvinyl pyrrolidone. The remaining limitations of claim 1 describe a measure of how much hydrogen peroxide can be eluted from the membrane.

Shimagaki teaches hollow fiber membranes and apparatus made from polysulfone and PVP – see examples, with about 40 microns thickness, about 33% PVP content. This reference does not explicitly state the amount of hydrogen peroxide that can be eluted from the membrane, or its UV absorbance. However, since the membrane otherwise has the same composition as well as the starting materials, the residual hydrogen peroxide (from PVP starting material) as well as the UV absorbance resulting from it are assumed to be inherently the same as that of the applicant's.

Cross-linked – see column 11, starting at line 42. The PVP is also insolubilized – same molecular weight of PVP, as well as cross-linked.

Newly added claims 18-23 (amendment 1/22/10) recite further limitations on the process of making the product, which is not patentable: "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability

is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re *Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

Argument that the method of analysis of the residual hydrogen peroxide in the membrane is not taught by the reference is not persuasive. Claim is for a hollow fiber device, which is taught by the reference. The residual hydrogen peroxide – there is no evidence that the reference membrane has residual hydrogen peroxide in an amount more than 5 ppm, or that it will show any more than 5 ppm of hydrogen peroxide when tested using the recited procedure. Applicant has failed to provide any evidence that the reference membrane would have a hydrogen peroxide content of more than 5ppm, or that it would elute more than 10 ppm of PVP. Just because the reference does not explicitly teach of storage stability, it is erroneous to assume that the membrane of the reference would have poor storage stability. Argument that office action makes no arguments why the claimed subject matter is rendered obvious: this is erroneous – the office action has made it very clear that the residual hydrogen peroxide content in the reference membrane would be inherently the same – same composition and starting material. The express, implicit, and inherent disclosures of a prior art reference may be relied upon in the rejection of claims under 35 U.S.C. 102 or 103. "The inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." In re Napier, 55 F.3d 610, 613, 34 USPQ2d 1782, 1784

(Fed. Cir. 1995) (affirmed a 35 U.S.C. 103 rejection based in part on inherent disclosure in one of the references). See also In re Grasselli, 713 F.2d 731, 739, 218 USPQ 769, 775 (Fed. Cir. 1983). Where applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection. "There is nothing inconsistent in concurrent rejections for obviousness under 35 U.S.C. 103 and for anticipation under 35 U.S.C. 102." In re Best, 562 F.2d 1252, 1255 n.4, 195 USPQ 430, 433 n.4 (CCPA 1977). This same rationale should also apply to product, apparatus, and process claims claimed in terms of function, property or characteristic. Therefore, a 35 U.S.C. 102/103 rejection is appropriate for these types of claims as well as for composition claims.

Response to Arguments

Applicant's arguments filed 1/22/10 have been fully considered but they are not persuasive.

Arguments are not commensurate in scope with the claims, because the claims do not recite the argued details for making the membrane that would result in the applicant's stated less than 5 ppm peroxide. However, even if included, such process limitations would not overcome the prima facie case of anticipation/obviousness without secondary evidence that the reference product do not exhibit the claimed features of elution of peroxide.

Applicant's arguments about the comparative examples having high amounts of extractable peroxides would not constitute evidence that the reference hollow fibers would have such extractables. There is no evidence linking the comparative examples to the Shimagaki hollow fibers.

Applicant uses the same PVP as is used by the reference – source such as BASF. Therefore, the starting polymer in Shimagaki also would have low peroxide content as argued. The reference teaches washing the membrane, which would remove any extractables. Thus there is no reason to believe that the Shimagaki hollow fibers would have peroxide content higher than what applicant's membrane would have.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Krishnan S. Menon whose telephone number is 571-272-1143. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on 571-272-0579. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Krishnan S Menon/

Primary Examiner, Art Unit 1797